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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,866	10/10/2006	Dirk Werling	E072 1070.1	9180

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EXAMINER	
HORNING, MICHELLE S	
ART UNIT	**PAPER NUMBER**
1648	

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09/13/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,866	WERLING, DIRK	
	Examiner	Art Unit	
	MICHELLE S. HORNING	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/28/2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *73-75* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *73-75* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 73-75 are under current examination.

This action is responsive to communicated filed 4/28/2011.

To allow entry of the new rejections below, this action is non-final.

Any rejection(s) and/or objection(s) not reiterated herein have been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 74 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a viral pathogen wherein the antigen is F protein of RSV, does not reasonably provide enablement for an F protein of RSV from any and all viruses (excluding RSV), fungi, protozoa and helminthes pathogens or a tumor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Enablement is considered in view of the *Wands* factors.

Nature of the invention. Claim 74 is directed to: an immunogenic compound, the compound comprising (i) HIV gp120 and (ii) an antigen, wherein *the antigen is an antigenic component of a tumor or a pathogen* of the companion animal or the farm animal, wherein the *antigen elicits an immune response to the tumor or the pathogen*,

wherein said pathogen is selected from the group consisting of *viruses*, *fungi, protozoa and helminthes, wherein the antigen is F protein of respiratory syncytial virus (RSV).*

Scope of the invention. As written, the claim encompasses a wide scope of sources from which the RSV F protein may be derived, including an antigen that is an antigenic component of a tumor or a pathogen, wherein the pathogen is selected from any and all viruses, fungi, protozoa and helminthes.

State of the prior art. RSV is well described by the prior art both functionally and structurally. The prior art describes RSV as the most common cause of severe lower respiratory tract infection in human infants wherein the two major glycoproteins of FSV, F and G, play a crucial role in virus uptake/penetration by the cell; see Werling *et al.* (*J. Leukocyte Biology*, 1999-cited by IDS). The prior art also provides the genome of respiratory syncytical virus; see GenBank AF013254 cited by IDS. The prior art, however, does not provide an F protein of RSV may be derived from a tumor or any and all viruses (excluding RSV), fungi, protozoa and helminthes such that the F protein of RSV is an antigenic component of a tumor or a pathogen wherein the F protein of RSV elicits an immune response to the tumor or the pathogen (any and all viruses, fungi, protozoa and helminthes).

Guidance in the specification and working examples. The instant specification describes a compound for the immunization of an animal comprising a moiety which selectively binds to a bovine dendritic cell and the conjugated antigen, RSV F protein. The moiety, HIV gp120, selectively binds DC-SIGN; see abstract. The instant specification provides adequate description for the isolation of bovine DC-SIGN DNA

sequences (see p. 36, Example 7) and adequately shows that the bovine DC- SIGN successfully binds gp120 protein which successfully leads to an immune response to antigen RSV F protein (see p. 28-31). No guidance is or working examples are provided in obtaining an F protein of RSV from unrelated tumors or unrelated pathogens.

Predictability of the art. In view of the lack of both the prior art teachings and the guidance in the instant specification in supporting an RSV F protein from multiple unrelated sources, there is no way one could predict how to derive an RSV F protein from a tumor or any and all unrelated viruses, fungi, protozoa and helminthes as required by the claim.

Amount of experimentation necessary. Much undue experimentation would be necessary in order to determine if an RSV F protein may be derived from multiple unrelated sources as required by the claims, if such is possible at all.

Given the discussion above, it would require undue experimentation for the ordinary artisan to perform the full scope of the method as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 73-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Patterson *et al.* (*Biochem. and Biophys. Res.*

***Com.*, 2001-previously cited) and Kurt-Jones *et al.* (*Nature Immunology*, 2000-cited by IDS).**

The claims are drawn to (in part): an immunogenic compound, the compound comprising (i) HIV gp120 and (ii) an antigen, wherein the antigen is F protein of RSV; see claims 73-75. Also see claim 73 claiming that the HIV gp120 and the antigen each comprises a polypeptide and are present in the same polypeptide chain.

Patterson *et al.* describes a hybrid protein comprising a native gp120 protein fused to an HBcAg, meeting the limitation that the HIV gp120 and antigen are present in the same polypeptide chain; see claim 73, in part. The authors teach that linking native gp120 to a potent immunogen improves immunogenicity of gp120 vaccines in eliciting antibodies (p. 639, col. 1). The authors concludes that the disclosed hybrids should be a useful starting point for linking gp120 to a variety of carrier proteins capable of enhancing immunogenicity, while retaining the native structure needed to elicit broadly crossreactive neutralizing antibodies against HIV virus (p. 642, col. 2).

Patterson *et al.* does not disclose using an F protein of RSV as the immunogen in the hybrid protein; see claims 73-75.

Kurt-Jones *et al.* characterizes and describes the immunogenic responses of the F protein of RSV (see p. 399; see whole document).

It would have been obvious to one of ordinary skill in the art to combine the references above and substitute the HBcAg for the F protein of RSV in the hybrid/fusion protein taught by Patterson *et al.* One would have been motivated to do so for the advantage of making a multivalent antigen. One would have also been motivated to use

both the known and characterized RSV F protein for the advantage of enhancing immunogenicity of gp120 vaccine as taught by Patterson *et al.*

There would have been a reasonable expectation of success given the underlying materials and methods are widely known and commonly used as evidenced by the applied prior art (*e.g.* making a hybrid protein, using known and characterized antigens, *etc.*). The invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claim is allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE S. HORNING whose telephone number is (571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ZACHARIAH LUCAS can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MICHELLE S HORNING/
Examiner, Art Unit 1648